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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,198	11/27/2001	Anders Bjorling	P01,0434	9390

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,198

Applicant(s)

BJORLING ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-21 and 32-55 is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9,11-14,22,23 and 27-31 is/are rejected.
- 7) ☒ Claim(s) 3-5,8,10 and 24-26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: ____

DETAILED ACTION

Claim Objections

1. Claim 31 is objected to because of the following informalities: the term "said remainder of electrodes" lacks antecedent basis. The examiner will assume the applicant intended claim dependency from claim 30 and not claim 23 when considering the claim on the merits. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 11, 12, 22, 23 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Glace (Pat. No. 5,158,092).

Regarding claim 1, Glace discloses a method wherein a plurality of electrodes (1, 2) at a tip of a cardiac lead (6) are placed in contact with cardiac tissue so that all of the electrodes are simultaneously in substantially fixed contact with the tissue. Individual unipolar electrical signals are obtained that exhibit a time relationship relative to each other (note Fig. 5). The time relationship is analyzed to obtain an analysis result (note for example col. 2, lines 18-46), and a signal is generated indicating a cardiac rhythm abnormality dependent upon said analysis result. In this case, the examiner considers the determination of the emergence point of the tachycardia to be an indication of a cardiac rhythm abnormality. The examiner also considers the electrical signals obtained by the electrodes to be unipolar in nature by virtue of the fact that each electrode produces an independent electrical signal (see Fig. 5 wherein electrode one produces signal 23, electrode two produces signal 24, and so on). If electrodes one and two were combined in a bipolar arrangement, each pair would result in one signal.

Regarding claim 22, comments made above in the rejection of claim 1 apply here as well. Although Glace does not specifically refer to a QRS detector, the examiner considers the detection circuitry of Glace to be capable of detecting the QRS signal by virtue of the fact that it can detect ventricular activation signals.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glace (Pat. No. 5,158,092).

Concerning claim 7, Glace does not elaborate on what aspect of the unipolar electrical signal is identified in order to determine the time relationship between signals. Fig. 5 appears to show that the rising edge of the activation signal is employed to determine the fiducial point from which phase measurements are calculated (note also col. 6, lines 12 and 13). In any event, those of ordinary skill in the art would have considered the exact point at which to base measurement on to be a matter of obvious design. Clearly both maximum slew rate and maximum negative derivative are old and well-known parameters useful in determining valid signals and more specifically, rising and falling edges. Any parameter useful in filtering out noise or spurious signals and allowing one to accurately obtain a landmark point from which to base measurement on, would have therefore been considered obvious by any ordinarily skilled artisan.

Similarly for claim 9, it is old and well-known in the cardiac signal processing arts to determine the slope of a signal and act on any signal that meets a set threshold indicative of a valid slope and thus a valid signal.

6. Claims 13, 14, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glace in view of Desai (Pat. No. 5,433,198).

Regarding claims 13 and 14 and claims with similar limitations, although Glace discloses an arrangement wherein the electrodes are disposed about the periphery of a disc sans a center electrode, those of ordinary skill in the art would have recognized the exact arrangement to be a matter of obvious design as long as the basic concept of the invention (i.e., allowing determination of the phase differences between electrodes as a result of the depolarization vector) was not interfered with. Desai disclose a related system wherein such an arrangement is incorporated (note for example Fig. 2B). To include a center electrode as shown by Desai to allow one to pinpoint the origin of a tachyarrhythmia such as disclosed in col. 10, lines 10-34 would have therefore been considered a matter of obvious design given their known use in related systems.

Allowable Subject Matter

7. Claims 15-21 and 32-55 are allowed.

With reference to claim 15, the prior art does not disclose or suggest a teaching for modifying any reference to include the steps of storing a detection pattern as a template and comparing subsequently obtained detections to the template and generating a signal indicating a cardiac rhythm abnormality dependent upon the comparison result.

A related comment applies to claim 32.

8. Claims 3-5, 8, 10 and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
December 29, 2003



KENNEDY SCHAETZLE
PRIMARY EXAMINER